Remarks

Claims 1, 11, and 64-79 are pending in this application and are presented for the Examiner's review and consideration. Claims 1, 11, and 64 have been amended and claims 65-79 have been added. Applicant believes the claim amendments, additions, and accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

35 U.S.C. § 102(b) Voss.

Claim 1 was rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,347,234 to Voss. ("Voss"). For the reasons set forth below, Applicant respectfully submits that claim 1 is not taught or suggested by Voss.

Voss discloses hygienic devices and more particularly improved hygienic applicators for tampons or suppositories. (Col. 1, lns. 8-10). The device 10 includes a hygienic applicator 11, a portion of which is a hollow, generally cylindrical outer tube 12 which is relatively thin walled and inherently weak and which includes a generally conical forward end 14. (Col. 3, lns. 69-73). The applicator 11 also includes a tampon-ejecting tube 20 disposed within the outer tube 12. (Col. 4, lns 7-9). The tapered, generally conical forward end 14 of the outer tube may be partially frusto-conical, as illustrated in FIGS. 1-4, and preferably, is formed of tightly abutting, symmetrically disposed folds 32, arranged in a dove-tailed configuration. (Col. 4, lns 49-54). The tube material lying on the fold lines 34 between adjacent folds 32 at the forward end 14 can be sufficiently weakened by repeated folding and unfolding thereof so that in the finished product little forward thrust or force need be applied to the inner tube 20 in order to eject the tampon 16 from the forward end 14. (Col. 4, ln. 75 – col. 5, ln. 5). The hygienic device includes an improved applicator which imparts to the device an improved efficiency of performance,

including improved ease with which a tampon or other hygienic medium can be ejected from the device into the desired body cavity. (Col. 3, lns. 29-26). As such, Voss does not disclose that the forward end pierces an imperforate surface on the body for insertion of the tampon (suppository). Additionally, the shape of the forward end and the weakness of the folds prevent the Voss device from piercing an imperforate surface on the body tissue.

In contrast, the present invention discloses that an insertion assembly 20 is used to position an anchor 22 relative to body tissue 24. (Page 4, lns. 25-26). The inserter assembly 20 includes a tubular outer member 30. (Page 5, lns. 5-6). The tubular outer member 30 has a passage 32 through which the anchor 22 moves into the body tissue 24. (Page 4, lns. 6-7). A leading end portion 62 of the tubular member 30 is operable between a closed condition and an open condition. (Page 6, ln. 26 –page 7, ln. 1). When the tubular outer member 30 is in the closed condition FIG. 1, a point 66 is formed at the end of the tubular outer member 30. (Page 8, lns. 10-13). This point can initiate the formation of an opening in an imperforate surface 68 on the body tissue 24. (Page 8, lns. 13-15).

Independent claim 1 now recites an apparatus for use in positioning a suture anchor relative to body tissue. The apparatus includes a tubular member through which the anchor is movable. The end portion is operable between a closed condition blocking movement of the anchor through the end portion into the body tissue and an open condition in which the end portion is ineffective to block movement of the anchor into the body tissue. In the closed position, the end portion of the tubular member has a pointed end for piercing an imperforate surface on the body tissue.

In light of the foregoing, independent claim 1 is respectfully submitted to be patentable over Voss. As new claims 65-71 depend from claim 1, these dependent claims necessarily include all the elements of their respective base claim. Accordingly, Applicant respectfully submits that the dependent claims are also allowable over Voss at least for the same reasons.

35 U.S.C. § 102(b) Clancy, III.

Claims 11 and 64 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,681,352 to Clancy, III. ("Clancy"). For the reasons set forth below, Applicant respectfully submits that claims 11 and 64 are not taught or suggested by Clancy.

Clancy discloses a system for securing a surgical tie to a bone via an elongated anchor affixed within the cancellous region of the bone. (Col. 3, lns. 31-33). The tool 100 generally includes a two-piece housing 102 having first and second parts 102a-102b that are three-dimensional mirror images of each other. (Col. 3, lns. 41-44). The tool 100 also includes a deflecting nose 116, which is held in place between the housing parts 102a-102b. (Col. 4, lns. 9-10). The nose 116 and anchor 310 together are placed into a slot 320 of the housing part 102b. (Col. 4, lns 49-50). The nose 116 has multiple curved resilient fingers 800 integrally formed on the flange 324. (Col. 5, lns. 44-51). The resilient fingers 800 part about the anchor 310, permitting the anchor 310 to exit the nose 116. (Col. 6, lns. 61-63).

The flange 324 has defined therein a central aperture 802, which extends downward into a central chamber (not shown) between the resilient fingers 800. (Col. 5, lns. 45-48). The chamber is sized to slidably accommodate the anchor 310, the chamber cross-sectional area being slightly larger than the lateral cross-section of the anchor 310. (Col. 5, lns. 48-51).

"Unlike the tool 100, preparation of the patient (not shown) is somewhat more involved. First, an incision is made to expose the region of bone where the anchor is to be installed. Then, referring to FIG. 9, a hole 900 is drilled through the hard cortical 902 region of bone. The hole 900 extends sufficiently into the relatively soft cancellous layer 904 sufficiently to receive the anchor 310, as explained below. The hole 900 has a diameter just slightly larger than the nose 116." (Col. 6, lns. 38-46).

"Having drilled the hole 900, the tool 100 is aligned with the hole 900. Then, the tool 100 is moved in a direction 906 (toward the bone) until the nose 116 is inserted into the hole 900 as shown in FIG. 9. In this position, the nose 116 protrudes slightly past the cortical 902 into the cancellous region 904 of bone." (Col. 6, lns. 40-53).

Clancy does not disclose that the central aperture expands as the anchor is move

therethrough. Additionally, the nose of the tool does not pierce the body of the patient. Instead the nose of the tool is inserted into a predrilled hole in the body of the patient.

In contrast and as noted above, the, present invention discloses that an insertion assembly 20 is used to position an anchor 22 relative to body tissue 24. (Page 4, lns. 25-26). The inserter assembly 20 includes a tubular outer member 30. (Page 5, lns. 5-6). The tubular outer member 30 has a passage 32 through which the anchor 22 moves into the body tissue 24. (Page 4, lns. 6-7).

As the anchor 22a is moved axially through the tubular outer member 30a (FIG. 6) under the influence of force applied against the anchor by the inner member 54a, the anchor expands the tubular outer member from the closed condition to an open condition. Thus, force applied against the inside of the passage 32a results in resilient expansion of the passage from the closed condition to the open condition.

A leading end portion 62 of the tubular member 30 is operable between a closed condition and an open condition. (Page 6, ln. 26 –page 7, ln. 1). When the tubular outer member 30 is in the closed condition FIG. 1, a point 66 is formed at the end of the tubular outer member 30. (Page 8, lns. 10-13). This point can initiate the formation of an opening in an imperforate surface 68 on the body tissue 24. (Page 8, lns. 13-15).

Independent claim 11 recites a method of positioning an anchor relative to body tissue. The method includes positioning an end portion of a tubular member relative to body tissue with the end portion of the tubular member in a closed condition at least partially blocking a passage in the tubular member. The tubular member is moved into the body tissue by piercing the body tissue with an end portion of the tubular member.

In light of the foregoing, independent claim 11 is respectfully submitted to be patentable over Clancy. As new claims 72-79 depend from claim 11, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that these dependent claims are also allowable over Clancy at least for the same reasons.

Claim 64 recites a method of positioning an anchor relative to body tissue. The method includes positioning an end portion of a resilient tubular member relative to body tissue with the

end portion of the resilient tubular member in a closed condition at least partially blocking a passage in the resilient tubular member and resiliently expanding the resilient tubular member by moving a tubular expansion member along a passage in the resilient tubular member. As noted above, Clancy does not disclose a resilient tubular member which is resiliently expanding by moving a tubular expansion member along a passage in the resilient tubular member. Rather, Clancy only discloses a nose having a flange which defines a central aperture extending downward into a central chamber. The chamber is sized to slidably accommodate the anchor, the chamber cross-sectional area being slightly larger than the lateral cross-section of the anchor.

In light of the foregoing, independent claim 64 is respectfully submitted to be patentable over Clancy.

Double Patenting

Claim 11 and 64 were rejected under the judicially created doctrine of double patenting over claim 9 of US Patent No. 6,364,897.

In response and in order to expedite the prosecution of this application, Applicant submits herewith a Terminal Disclaimer to obviate these double patenting rejections. It should be understood that the Terminal Disclaimer is being filed to expedite prosecution and should not be construed as an admission that the Terminal Disclaimer is necessary.

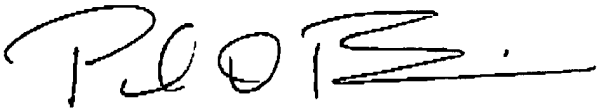
Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested. If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

A fee of $55.00 is believed due for the accompanying Terminal Disclaimer and a Fee Transmittal Sheet including this fee is submitted concurrently herewith. Please charge any

required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 782-A02-012-3).

Respectfully submitted,



Paul D. Bianco, Reg. # 43,500

Customer Number: 33771
Paul D. Bianco
FLEIT KAIN GIBBONS GUTMAN BONGINI & BIANCO
601 Brickell Key Drive, Suite 404
Miami, Florida 33131
Tel: 305-931-9620; Fax: 305-931-9627
e-mail: pbianco@focusonip.com